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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/661,305	09/13/00	SATO	T P19977

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HM12/1024

EXAMINER	
DAVIS,N	
ART UNIT	PAPER NUMBER
1642	10

DATE MAILED: 10/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/661,305	Applicant(s) SATO ET AL.	
	Examiner Natalie A. Davis	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 August 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement received 8 January 2002 and the supplemental disclosure received 5 April 2001 has been considered. A signed copy is attached hereto.

Applicant's election with traverse of Group I, claims 3-5 in Paper No. 9 is acknowledged. The traversal is on the ground(s) that the invention of Group I encompasses the claims of Groups II-II and could be searched and examined at the same time without a serious burden, even though Group I is directed to a protein and Group II is directed to a DNA sequence and because the examiner has not sufficiently defined "materially different to justify a restriction requirement. This is found to be persuasive and Groups I and III will be rejoined with Group II. Therefore, claims 1-6 are being examined.

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-6 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility.

The claims are drawn to an agent for use in screening medicament for the treatment, prevention and/or diagnosis of an apoptosis-related disease, which comprises an apoptosis related protein that binds to NADE or a DNA encoding it. The claims are further drawn to a method of screening for a medicament comprising detecting the interaction of an apoptosis related protein and NADE in the presence and absence of the medicament to be tested and choosing the medicament having an effect on the interaction. The claims are further drawn to a medicament for the treatment, prevention, and/or diagnosis of an apoptosis-associated disease, which is chosen by the method of claim 3.

2. There is no art on record that discloses effecting the ability of NADE to bind an apoptosis related protein could lead to the treatment, prevention and/or diagnosis of an apoptosis-related

disease, or that any medicament, which effects the interaction of NADE with an apoptosis related protein would be a candidate for treatment, prevention and/or diagnosis of an apoptosis-related disease, or how to select for said medicament. There is no record in the art that indicates that NADE plays a role in the treatment prevention and/or diagnosis of an apoptosis-related disease and the specification indicates that NADE only binds to the nerve growth factor receptor that induces apoptosis. The specification does not give any guidance or exemplify that NADE alone or in combination with any apoptosis related protein, other than p75NTR, would lead to the induction or regulation of apoptosis. In order for apoptosis related disease to be diagnosed, treated, and/or prevented, it must be certain that NADE interaction with apoptosis associated proteins or changes in interaction is indeed indicative of an apoptosis disease and not some other disease. Furthermore, the disclosure does not indicate which diseases the medicament may be used to treat, prevent, and/or diagnose. Since there is no evidence in the art teaching and the specification does not exemplify or give any guidance as how to make and use the invention, the invention lacks specific and credible utility and the asserted utilities also lack credibility.

3. The specification does not disclose any objective evidence regarding the successful treatment, prevention, and/or diagnosis of any disease in any subject by the administration of the claimed medicament into the subject. Until some specific and substantial significance, as indicated above, can be attributed to the claimed invention, one of ordinary skill in the art would be required to perform additional experimentation in order to determine a use for the claimed invention. Thus, there is no immediate apparent or "real world" utility as of the filing date and the claimed invention as disclosed does not meet the requirements of 35 U.S.C. § 101 as being useful.

4. Claims 1-6 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 3 is drawn to a method of screening for a medicament, comprising detecting interaction between NADE and an apoptosis related protein in the presence of a medicament. This is indefinite since it is not clear how detecting the interaction in the presence of a medicament is indicative of screening.

7. It is indefinite in the recitation of "effect" in claim 4 as the metes and bounds for the interaction between NADE and an apoptosis related protein. There is no indication of what effect the medicament must make on the interaction and to what degree the effect must make.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether undue experimentation is required are summarized *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). They include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claims are drawn to a method of screening for a medicament comprising detecting the interaction of an apoptosis related protein and NADE in the presence and absence of the medicament to be tested and choosing the medicament having an effect on the interaction. The

claims are further drawn to a medicament for the treatment, prevention, and/or diagnosis of an apoptosis-associated disease, which is chosen by the method of claim 3.

The specification states that NADE binds to the nerve growth factor receptor (p75NTR) and participates in the induction and regulation of apoptosis and identification of a protein, which binds to NADE and associates with apoptosis mediated by NADE is expected to be useful for treatment, prevention, and/or diagnosis of apoptosis-associated diseases (page 2).

9. The instant disclosure fails to meet the enablement requirement for the following reasons: The disclosure does not give any guidance as to what effect the medicament must make on the NADE/apoptosis related protein interaction that indicates that the medicament will function as contemplated, thus one of skill in the art would not know how to use the claimed method to select for a medicament that will function as contemplated. The disclosure does not exemplify or give any guidance on how to use a medicament that functions as contemplated, thus it would be unpredictable to use the method of claims 3-5 to screen for a medicament, which may be used to treat, prevent, and/or diagnose an apoptosis associated disease and it one of ordinary skill in the art would not be able to make or use the medicament as claimed.

10. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for agent 14-3-3 and NIK/HGK, which is an apoptosis related protein that binds to NADE, does not reasonably provide enablement for an agent beyond those mentioned supra and that the agent may be used to screen for a medicament. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claims 1-2 are drawn to an agent, which comprises an apoptosis related protein, which binds to NADE or a DNA that encodes the protein thereof, which is used to screen medicament.

The disclosure exemplifies *in vivo* binding of NADE to 14-3-3 and NIK/HGK proteins (pages 19-20), and show how nerve growth factor promotes NADE binding with 14-3-3 (page 21).

11. The instant disclosure fails to meet the enablement requirement for the following reasons:

The disclosure does not give any guidance or exemplification of an apoptosis related protein or DNA encoding the said protein or than 14-3-3 and NIK/HGK is capable of binding NADE and there is no record in the art teaching it. Since there is no evidence in the art teaching

NADE binding to apoptosis related proteins, it would be unpredictable to make or use the claimed agent. Furthermore, there is no guidance or exemplification showing NADE and the claimed agent in a screening process for a medicament that may be used for treatment, prevention, and/or diagnosis of an apoptosis disease. Accordingly, one of ordinary skill in the art would be required to undue experimentation in order to select and use the invention as claimed.

12. Claims 1-2 and 6 are rejected under 35 U.S.C. 112, first paragraph. The instant specification does not contain a written description of the invention in such full, clear, concise, and exact terms or in sufficient detail that one skilled in the art can reasonably conclude that applicant had possession of the claimed invention at the time of filing.
Vas-Cath Inc. v. Mahurkar (CA FC) 19 USPQ2d 1111 (6/7/1991) clearly states that "written description" of invention required by first paragraph of 35 U.S.C. 112 is separate and distinct from that paragraph's requirement of enabling disclosure, since description must do more than merely provide explanation of how to "make and use" invention; applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed. An applicant shows possession by describing the claimed invention with all it limitations using such descriptive means as words, structures, diagrams, and formulas. Also, description of an actual reduction to practice, or by showing the invention was "ready for patenting," or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention at the time of filing.

The claims are drawn to an agent that may be used to screen for medicament for the treatment, prevention and/or diagnosis of an apoptosis-related disease, which comprises an apoptosis related protein that binds to NADE or a DNA encoding it. The claims are further drawn to a medicament for the treatment, prevention, and/or diagnosis of an apoptosis-associated disease, which is chosen by the method of claim 3.

13. The specification discloses that the medicament for treatment comprises as an active ingredient, a substance for controlling intracellular expression or amount of the apoptosis related protein which binds to NADE, including substances controlling transcription or translation of a gene of the apoptosis-related protein, antisense oligonucleotides of the gene, antibodies

recognizing the protein, and the like (page 10). However, there are no examples disclosed that conveys to one of skill in the art that the applicant was in possession of any agent that may be used to screen for medicament or any medicament for the treatment, prevention and/or diagnosis of an apoptosis-related disease. There is no descriptive information, such as how to make and administer the medicament or complete detailed description of the function of claimed invention indicating that the claimed agent or medicament was indeed identified and used for the methods and/or intended methods as disclosed. Furthermore, there is no guidance for the treatment, prevention and/or diagnosis of any apoptosis-related disease. There is no actual reduction to practice, as there is no evidence regarding the successful treatment, prevention, and/or diagnosis using an agent or medicament or any exemplification that any medicament was chosen by the method of claim 3. Thus, one skilled in the art would not be able to recognize from the disclosure that the applicant was in possession of claimed agent and medicament.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Davis whose telephone number is 703-308-6410. The examiner can normally be reached on M-F 8-5:30 (every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4315 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Natalie A. Davis, Ph.D.
October 22, 2001

GEETHA P. BANSAL
PRIMARY EXAMINER